PTFE valved Conduits for RVPA Reconstruction: Do they outperform xenografts and allografts?

(Invited Commentary)

John W. Brown M.D. Professor of Cardiothoracic Surgery
Indiana University School of Medicine

Department of Surgery
Division of Cardiothoracic Surgery
545 Barnhill Drive, Indianapolis, Indiana 46202

Telephone and Fax: (317) 944-7150, (317) 274-2940

Email: jobrown@iupui.edu

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John W. Brown receives consultation fees from Medtronic, Inc. for consultation of the Contegra conduit and Harmony Percutaneous valves.

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Doctor Miyazaki, Professor Yamagishi and colleagues are to be commended for their excellent PTFE valved RV-PA conduit clinical results, which are illustrated in this manuscript.

Allografts and bovine jugular vein conduits have been the most popular RVPA conduits in the US and Europe for the last 2 decades. These conduits function well for a few years and their durability has improved. Their limited long-term durability, however, necessitates multiple conduit exchanges over the patient's lifetime. Allografts are generally not available in Japan, and the bovine jugular vein conduit has only become available in the last 2-3 years. Japan's need for a RVOT reconstruction material stimulated their early interest in PTFE as a pulmonary valve substitute.

Professor Yamagishi first demonstrated the use of 0.1mm PTFE material (designed and developed for pericardial closure for making a synthetic pulmonary valve leaflet and published its use as a monocusp valve in 1993. We adopted and modified the monocusp technique 24 years ago and continue to use it for pulmonary valve reconstruction in patients requiring a transannular patch. Soon after their monocusp experience, Miyazaki & Yamagishi began making handmade conduits using 0.1mm PTFE for leaflets, and a thicker tubular PTFE for the conduit. They recently added sinuses and fan-shaped leaflets since 2010 based on hydrodynamic experiments in a pulse duplicator.

This manuscript summarizes the outcomes of 902 patients with handmade PTFE valved conduits constructed by a single surgeon. The conduits included bulging sinuses and fan-shaped PTFE leaflets in 9 different sizes (8-24mm in diameter) and were implanted in children and adults at 65 Japanese hospitals between 2001-2015. The mean patient age was 3.9 years and mean weight was 12.5 kg. The patients had a variety of congenital cardiac malformations requiring RVOT reconstruction. The patients' hospital survival was excellent at 98%, and late survival was 95.5% out to 15 years.

They compared patients by age greater or less than 2 years of age. Those< 2 years of age (n=292) had a freedom from conduit replacement of 90% and 74% at 5 and 10 years, respectively. Freedom from conduit replacement in the group older than 2 years was >95% at 10 years.

Their conduits showed excellent freedom from infection, stenosis, and regurgitation (>95%) during follow-up (median=4.8 yrs.). Fifty-five conduits (6%) were replaced mostly for outgrowth or stenosis proximal or distal to the valved conduit. Fifty-three patients required balloon catheter intervention for proximal and/or distal stenosis.

This large Japanese multicenter experience with a handmade conduit may not be immediately transferable to the US and Europe because the FDA and other governing bodies are not likely to approve handmade valved conduits due to inconsistent quality control. The authors' experience, however, is an excellent proof of concept and will open the door for industry to provide a consistent product for congenital heart surgeons.

PTFE valved conduits as shown in this manuscript show real promise as an alternative to currently available RVPA conduits. Longer follow-up will be necessary to see if these conduits continue to perform as well as the authors report here.